

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/5/2010 has been entered.

Claims 1-4, and 6-14 are being considered on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4 and 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (2000, Soy protein fortification affects sensory, chemical and microbiological properties of dairy yogurts; hereinafter R1) in view of Zhang et al. (1997, Effect of soy protein hydrolysate (SPH) on proliferation of lactic acid bacteria; hereinafter R2) and JP 59082050 (Abstract, hereinafter R3).

3. R1 discloses making yogurts with milk (10% solids) containing 1-5% (w/w) soy protein (Page 1244, materials and methods). Given that milk contains about 3% protein, the yogurt will contain about 3% milk protein as presently claimed.

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4. R1 teaches using a yogurt starter culture including *Lactobacillus bulgaricus* and *Streptococcus thermophilus* (page 1245, Col. 1, Microbiology and instrumental measurements).

5. R1 discloses some of the disadvantages of incorporating soy protein isolate in yogurt. R1 discloses that increased fermentation times or lower final titratable acidities have been reported with soy based yogurts, presumably due to a lack of essential nutrients for the lactic acid bacteria. Apparent viscosity of fermented milk fortified to 18% total solids with soy protein isolate were significantly higher than the viscosity of the fermented milks fortified with non-fat dried milk at 18% total solids. Higher protein content of soy protein isolate compared to non-fat dried milk was attributed as the reason for higher viscosity of the product. R1 further discloses that color was different for yogurts containing 2.5-5% added soy protein. (page 1246, col. 2). R1 also discloses the flavor problems which might be imposed by soy protein to dairy yogurt. (page 1247, conclusion).

6. While R1 discloses yogurt product containing milk protein and soy bean protein, R1 is silent regarding the inclusion of soy protein hydrolysate and vegetable oil in the formulation.

7. R2 discloses the incorporation of soy protein hydrolysate (SPH) in fermented milk. R2 reports that the soy protein hydrolysate stimulates the growth of bacteria in the fermented product. R2 discloses that the hydrolysate can not only serve as a nutrition reinforcer, but also plays an important role in the yogurt manufacturing. (Abstract)

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8. Given that soy protein hydrolysate stimulates the growth of bacteria in the fermented product, it is clear that it can be a solution to the problem of increased fermentation time as discussed by R1.

9. Given that R1 and R2 disclose the inclusion of soy protein and protein hydrolysate in fermented milk, changing the ratio of hydrolyzed protein to non-hydrolyzed protein, as presently claimed, for optimization of sensory and processing factors is obvious and well within the skill of art.

10. R1 and R2 are silent regarding the use of vegetable oil in the formulation.

11. R3 discloses a pudding which is prepared by lactic acid fermentation of an aqueous emulsion of soybean protein hydrolysate. (Abstract)

12. R3 teaches using the protein hydrolysate at below 10% and more preferably 2-8%.

13. R3 teaches of using vegetable oil or animal fat at 1/4-1 times the dry protein content of the formulation. Assuming a 5% solids from the soy protein and 2% solids from the soy protein hydrolysate and about 3% solids from the milk protein for a total 10% protein, about 2.5-10% oil can be added to the formulation having so much protein.

14. Given that increased fermentation times or lower final titratable acidities have been reported with soy-based yogurt, due to a lack of essential nutrients for the lactic acid bacteria (R1, page 1246, col. 2, first 4 lines) and dairy yogurts fortified with soy protein exhibit higher viscosities than control dairy yogurts (page 1246, col. 2, first paragraph), incorporation of some soy protein hydrolysate to alleviate the viscosity and thickness problems brought about by unhydrolyzed soy protein would be obvious to

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those of ordinary skill in the art. Claim 11 requires that in the mixture of unhydrolyzed soy protein and soy bean hydrolysate, a minimum of 40% by weight should be provided by the hydrolysate , it is clear that this ratio can be experimentally optimized by an artisan in light of the amounts of protein hydrolysate disclosed by R3.

15. Given that a fermented yogurt product can be prepared containing hydrolyzed and unhydrolyzed soy bean protein, Stevens values (texture indication) and viscosities (thickness) can be calculated and optimized for a variety of fermented products in the ranges as presently claimed.

16. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a yogurt containing soy protein as taught by R1 and replace some of the unhydrolyzed soy protein with soy protein hydrolysate as taught by R2 and R3. One would do so to prepare a value added product made with more available, less expensive proteins such as soy bean protein having other nutritional benefits such as cholesterol lowering effects and provision of isoflavones. Absent any evidence to contrary and based on the combined teachings of the sited references, there would be a reasonable expectation of success in making a yogurt product as presently claimed.

Response to Arguments

Applicants arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

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1. Applicants argue that the Office appears to use classic hindsight approach to justify the rejection. They further argue that the "The Office states that the artisan "obviously knows" that some of the soyprotein isolate can be replaced with soyprotein hydrolysate to alleviate the viscosity change, the Office points to no support for this statement". Further, applicants state that what the Office appears really to be basing the rejection on is applicants' own disclosure and that is an improper use of hindsight.

a. A fair reading of the teachings of the cited references reveals the following facts.

- Incorporation of unhydrolyzed soy protein into yogurt, as disclosed by R1, was known at the time the invention was made. R1 further clearly discloses the drawbacks of including unhydrolyzed soy protein in yogurt.

- Incorporation of soy protein hydrolysate into yogurt was also known, as disclosed by R2.

- The properties of soy protein hydrolysate for alleviating the viscosity problems was also known at the time the invention was made. The phrase "obviously knows" refers to this state of knowledge in the art. Please see Tsumura et al. (US 6,126,973). They disclose that in order to control the viscosity increase caused by soy proteins, some of that protein can be replaced by soy protein isolate. (Col. 2, lines 47-63). Therefore the unexpected results that Applicants are referring to, i.e. control of viscosity through incorporating soy protein hydrolysate, was known in the art at the time the invention was made. It is further clear that this information was not adopted from Applicants' own disclosure as presently alleged.

Then the problem which was supposed to be solved at the time of the claimed invention, was a routine optimization of formulations leading to yogurt products. It should be realized that an invention introduces new concepts or new inventive steps in utilizing the existing knowledge in the art. In that capacity, an invention is different from a "new product".

Further, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Further, it is the examiner's position that the rejections are not based on hindsight but rather based on motivation to combine found in the references themselves. Moreover, those of skill in the art knew that problems, regarding the thickness and viscosity, caused by the incorporation of natural polymers such as proteins and starch could be solved by substituting a protein of the natural polymer with a hydrolysate. On the other hand; "obviousness under 103 is not negated because the motivation to arrive at the claimed invention as disclosed by the prior art does not agree with appellant's motivation", *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990), *In re Tomlinson*, 150 USPQ 623 (CCPA 1966).

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Therefore, combining unhydrolyzed soy protein and soy protein hydrolysate as disclosed by R1 and R2 would have been obvious to those of skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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